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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,369	08/17/2001	David A. Estell	GC626-2	4880

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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/932,369	Applicant(s) ESTELL ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on th cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *4 and 16-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Species polypeptide in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892; they have not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3 and 5-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble recites a method for determining the

absolute quantity of a target biopolymer whereas the body of the claim only recites determining the quantity of the target biopolymer.

Regarding claim 1, line 2 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 1, line 2 "crude solution" is vague and indefinite. It is unclear what applicant intends. There is no definition provided for the phrase in the specification.

Claim 1, part (c) "the biopolymer-fragment content" there is insufficient antecedent basis for this limitation. Is applicant resolving the biopolymer-fragment pairs or something else?

Claim 1, part (c) "the mixture" there is insufficient antecedent basis for this limitation. See also deficiency found in claim 1, part (e).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5-7 and 11-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Aebersold et al (US 2002/0076739).

Aebersold et al disclose a method for determining the absolute amounts of specific proteins (target biopolymer) in a complex mixture. Aebersold et al disclose adding a know amount of internal standard (analog), one for each specific protein in the mixture to be quantified, is added to the sample to be analyzed (p. 3, paragraph 0032). Aebersold et al disclose that the internal standard is an affinity tagged peptide that is identical in chemical structure to the affinity tagged peptide to be quantified except that the internal standard is differentially isotopically labeled, either in the peptide or in the affinity tag portion, to distinguish if from the affinity tagged peptide to be quantified (p. 3, paragraph 0032). Aebersold et al also disclose that isotopic label may be an isotopically stable isotope such as ^{2}H, ^{13}C, ^{15}N or ^{18}O (p. 4, paragraph 37). Aebersold et al disclose that the sample can be a cell or tissue lysate (paragraph 32) or cell homogenate. Aebersold et disclose digesting the proteins in the mixture with trypsin (fragmenting activity) (p. 7, paragraph 70, p. 19 paragraph 200 and scheme 1). Aebersold et al also teaches subjecting the proteins in the mixture to liquid chromatography and analysis with mass spectrometry (p. 7, paragraph 72, p. 19 paragraph 200 and scheme 1). Aebersold et al discloses that the mass spectrometry measurement readily differentiates between peptides originating from different samples because of the difference between isotopically distinct reagents attached to the peptides. The ratios between the intensities of the differing weight components of these pairs of peaks provide an accurate measure of the amount of the peptides in the original pools because the mass spectrometry intensity response to a given peptide is independent of the isotopic composition (p. 7, paragraph 76).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebersold et al (US 2002/0076739) in view of Chait (US 6,391,649).

See above for teachings of Aebersold et al.

Aebersold et al differ from the instant invention in failing to teach one of said target biopolymer and said analog is enriched in ^{15}N, and the other contains a natural abundance of N isotopes.

Chait et al disclose comparing the levels of proteins present in samples which differ in some respect from each other using mass spectrometry (abstract). Chait et al disclose culturing a first sample in a medium containing a natural abundance of isotopes and a second sample of same biological matter is cultured in a second medium in which the second medium is enriched in isotopes such as nitrogen-15, carbon-13, and oxygen-18 (col. 5, lines 35-58). Chait et al disclose that either medium may be modulated by a microbiological culture such as bacteria (col. 6, lines 15-20,). Chait et al disclose combining the two sample and treating with a detergent to digest the proteins (fragmenting activity) (Fig. 3, col 6, lines24-67) then separating the proteins (resolving) and subjecting the proteins to mass spectrometry to identify the proteins. Chait et al disclose that by culturing samples in this manner provides for methods of accurately comparing the levels of ionizable components of biological matter (col 3. lines 40-46) and that determining these levels allows is important in gaining an understanding of biological processes involved in living cells.

It would have been obvious to one of ordinary skill in the art to incorporate enrichment of ^{15}N and natural N isotopes as taught by Chait et al into the method of Aebersold et al because Chait et al teaches the same isotopes as Aebersold et al and also teaches digesting and separating proteins and subjecting them to mass spectrometry. Further, Chait et al shows that that by culturing samples in this manner

provides for methods of accurately comparing the levels of ionizable components of biological matter and that determining these levels allows is important in gaining an understanding of biological processes involved in living cells.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
August 29, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
09/09/03